

Animal Experimentation Ethics Committee Operating Procedures

Under the *Australian Code for the Care and Use of Animals for Scientific Purposes* (the Code) animal ethics committees must establish and document procedures that will enable compliance with the provisions of the Code, and relevant policies of the institution. The Code outlines particular areas that such procedures shall cover, and these are included in the Operating Procedures overseeing the Animal Experimentation Ethics Committee.

1. Assessment of Proposals

1. The AEEC meets every month except December. Proposals and amendments that are to be considered at a particular meeting must be submitted via ARIES by the last business day of the preceding month. Research ethics administration will allocate a protocol number to all new proposals.

2. Proposals, amendments, annual reviews, meeting agendas, minutes and items of general business are circulated electronically by Research Services to the Committee members in the first three business days of the month in which the meeting is to be held.

3. AEEC members read proposals, amendments, annual reviews and any circulated items of general business prior to the meeting, and then direct questions relating to proposals through the AEEC's Executive Officer to the primary investigator. Investigator responses to questions are sent back to the Committee via Research Services at animal.ethics@anu.edu.au. Replies are required by midday on the Friday preceding the meeting, although under extenuating circumstances, and at the complete discretion of Research Services and the Chair, replies from principal investigators may be submitted up to the morning of the meeting.

4. Collated questions and answers are provided to the Committee prior to the meeting, and are reviewed at the meeting to facilitate Committee discussion and decision-making. The AEEC may wish to speak to an investigator to clarify points and if this is required the investigator is notified in advance of the meeting. Where different concerns have been highlighted by members, the Chair will ensure a full discussion of all relevant issues within the remit of the Committee.

5. The Committee may:

- Approve a proposal without conditions; or
- Approve a proposal with conditions; or
- Defer a decision until receipt of further information or advice; or
- Not approve proposals.

When answers to questions are agreed to be satisfactory by all members, the proposal or amendment is approved and signed by the Chair at the completion of the meeting. If AEEC members are not satisfied with the standard of the proposal, the answers to questions, or if the proposal does not address ethical concerns, a decision may be deferred, extra information may be requested and circulated out of session or the proposal may be rejected. Where an investigator has outstanding reports due to the AEEC, such as annual reviews and expiry reports, a final decision may be held over until an investigator meets their reporting obligations.

6. The AEEC may approve minor amendments to proposals out of session. Research Services circulates the amendment electronically to all members; once approval is given by one member from each category (quorum), approval for the amendment is granted. If any member expresses concern, or major questions are raised, the amendment will be held over until the next formal Committee meeting. All out of session approvals must go to the next scheduled AEEC meeting for information.

7. The AEEC is only permitted to approve protocols for a three-year period. Investigators may apply for a one off three-month extension of a protocol. The extension requests must be submitted and reviewed as an amendment. A reason for the extension must be provided and it must be submitted before the protocol expiry date and in time for proper review by the AEEC.

8. Annual project reviews are considered on a case-by-case basis at the meeting and should be used to determine if projects may continue, be suspended, be modified or be discontinued.

9. In line with the Code Committee decisions are made on the basis of consensus, with the AEEC's definition of consensus being that all members agree concerning the point under consideration. Should this not be the case then a decision shall be held over to a subsequent meeting with further discussion in an attempt to reach consensus. The AEEC should explore with the applicant ways of modifying the project or activity that may lead to consensus. If consensus is not reached the Chair may move to a majority decision but only after members have been given time to review their positions, request further information and engage in further discussion.

10. The Chair of the AEEC meets quarterly with the ANU Deputy Vice-Chancellor (Research). The Chair has direct access to the Deputy Vice-Chancellor to raise specific issues of concern to the Committee, or regarding the operations and support of the Committee.

2. Quorate Meetings

AEEC meetings must be quorate as required by the Code, which requires that

- at least one member of categories A, B, C, and D must be present: and
- categories C plus D should represent not less than one third of those members present.

In addition to Category A, B, C, and D members the AEEC appoints one or more people responsible for the care of animals at the ANU. Observers may attend an AEEC meeting with the approval of the Chair and once confidentiality requirements are met. In exceptional circumstances where a face-to-face meeting is not possible a meeting may be conducted through the use of video linking or teleconferencing.

New protocols and annual reviews must only be considered at a quorate meeting. As per the Code, the Committee must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings.

3. Special Meetings

Special meetings may occur if circumstances dictate, for example if an unexpected adverse event requires consideration by the Committee. Special meetings are called at the discretion of the Chair.

4. Inspection of Sites and Delegation of Authority to Inspect Sites

The AEEC must inspect and approve all animal-holding facilities before they are occupied. The AEEC must be notified during the planning stages of new animal holding facilities. In accordance with the Code the AEEC must undertake an inspection of all animal-holding facilities at least annually. The AEEC may delegate a sub-committee of its members to inspect sites. It may also delegate its Executive Officer or a veterinarian to monitor projects at remote sites or where it requires a report concerning a specific project.

5. Resolution of Conflicts of Interest

Members are required to declare conflicts of interest. Conflicts of interest may arise when proposals in which AEEC members are involved are considered by the Committee; the member must declare the conflict of interest at that time. The system of questions directed to specific proposals prior to the meeting should circumvent potential problems. Where sensitive conflicts of interest involve a Committee member, that member, at the request of the Chair, will absent themselves from the meeting during consideration.

6. Handling of unexpected adverse events involving research animals

All unexpected adverse events involving the use of animals as part of ANU research and teaching activities must be reported to the AEEC. Please see the ANU's Unexpected Adverse Event Procedure for submitting adverse event reports.

Reports are received by the Research Services at animal.ethics@anu.edu.au and are immediately passed on to the AEEC and ANU Veterinarian electronically. Research Services will send an acknowledgement of receipt email to the person lodging the report. Depending on the seriousness or urgency of the event the AEEC may undertake one or more of the following:

- require that the project ceases until the matter has been investigated further;
- require further information from the principal investigator or other staff involved;
- require immediate veterinary intervention;
- require that the ANU veterinarian or nominated person visit a specific animal holding facility or site to make an assessment;
- defer the matter to the next scheduled meeting;
- call a special meeting to discuss the event.

7. Immediate use of Animals

The AEEC may give approval in advance, for the immediate use of animals, should they be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people. Wherever possible there should be communication between AEEC members, providing the relevant information to warrant the immediate use. Where timing does not allow the involvement of the full Committee the Chair may approve the immediate use of animals. For this purpose approval in advance is interpreted as approval in advance of an animal ethics application.

8. Dealing with Complaints & Non-Compliance

Processes for dealing with non-compliance and complaints regarding animal welfare or AEEC decisions as required under Section 5 of the Code are covered under separate ANU procedures.

Version	Date	Author	Approved By	Date
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